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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,754	06/12/2000	Robert G. Walsh	11998.20US01	4758

34379 7590 05/08/2003

ACORN CARDIOVASCULAR, INC.  
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MINNEAPOLIS, MN 55402

EXAMINER

GHAFOORIAN, ROZ

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 05/08/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/591,754

Applicant(s)

WALSH ET AL.

Examiner

Roz Ghafoorian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-22 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No.6432039 to Wardle.

Wardle teaches a device for treating cardiac disease of a heart having an upper and lower portions comprising a jacket 10 of flexible material defining a volume between an upper and lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole; and a delivery source 326 for delivery of one or more therapeutic agents to the surface of the heart.

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The flexible material is polyester. Furthermore it teaches a delivery source covering (coating) part of the jacket.

2. Claims 1, 12, 19, 21, 17 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 4827932 to Ideker et al.

Ideker teaches a device for treating cardiac disease of a heart having an upper and lower portions comprising a jacket 10 of flexible material defining a volume between an upper and lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole; and a delivery source 36f or delivery of one or more therapeutic agents to the surface of the heart. Were the delivery source comprises of a separable element from the jacket where the separable element is the bioadhesive. (Col. 6, lines 10-20, 30-35)

3. Claims 1, 3-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5713954 to Rosenberg et al.

Rosenberg teaches a device for treating cardiac disease of a heart having an upper and lower portions comprising a jacket of flexible elastic material defining a volume between an upper and lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and

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permit substantially unimpeded contraction of the heart during systole; and a delivery source for delivery of one or more therapeutic agents to the surface of the heart.

***Response to Arguments***

Applicant's arguments filed 3-11-2003 have been fully considered but they are not persuasive.


- a. Applicant's arguments with respect to claims 1, 19, 21 have been considered but are moot in view of the new ground(s) of rejection.
- b. Applicant alleges Wardel '039 does not teach a delivery source can be a coating. However the definition of coating is covering and as demonstrated by Wardel '039 in figure 14 the drug delivery line does cover parts of the jacket.
- c. Applicant alleges Ideker '932 fails to teach a bio-adhesive, however the applicant has failed to describe his definition of bio-adhesive in the specification and hence the examiner has interpreted bio-adhesive any device in which is biocompatible and functions as an adhesive, in which is taught by Ideker '932 in Col.6, lines 10-20, 30-35.
- d. In light of applicant's explanation regarding the difference between Girard '279 and applicant's application the double patenting rejection is withdrawn.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3230 for regular communications and 703-305-3230 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700

RG  
May 1, 2003